The YODA Project
Research Proposal Review - Final
(Protocol #: 2022-4981)

Reviewers:
☐ Nihar Desai
☐ Cary Gross
☐ Harlan Krumholz
☒ Richard Lehman
☒ Joseph Ross
☒ Joshua Wallach

Review Questions:
1. Is the scientific purpose of the research proposal clearly described?  Yes
2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?  Yes
3. Can the proposed research be reasonably addressed using the requested data?  Yes, or it's highly likely
4. Recommendation for this data request:  Approve

Comments:
1. The investigators have specified 10 primary outcome measures in their protocol and then list 6 additional outcomes measures (3 remission-based and 3 response-based) in the section for 'main predictor/independent variable(s)', but the main predictor/independent variable is the disease distribution (left-sided vs. extensive disease). Please clarify.
2. Will this study really include 10 co-primary endpoints/will the results for all these endpoints be emphasized equally?
3. Are Poisson regressions appropriate for all 10 outcomes? Additional information is necessary regarding the methods for the different endpoints.